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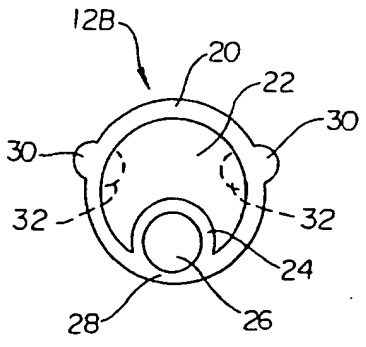
(54) Title: ECCENTRIC CATHETER SHAFT

(57) Abstract: An intravascular device having a tubular shaft with an outer wall and an inner wall which divides the outer wall into two or more lumens. The shaft also includes one or more regions of modified flexibility extending longitudinally along the outer wall. Absent the regions of modified flexibility, the inner wall would create an imbalance of material and flexibility about the center axis of the shaft. The regions of modified flexibility are positioned to reduce any such imbalance, thereby providing more uniform flexibility. The regions of modified flexibility also provide for more uniform torque transmission, and thereby reduce whipping effects. The regions of modified flexibility may comprise one or more regions of decreased wall thickness in the outer wall, one or more spines extending longitudinally along the outer wall, or a combination thereof.



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ECCENTRIC CATHETER SHAFT

Field of the Invention

The present invention generally relates to intravascular medical devices. More specifically, the present invention relates to multi-lumen intravascular medical devices such as balloon catheters.

Background of the Invention

Intravascular devices are commonly used to diagnose and treat various types of vascular disease. For example, coronary artery disease (CAD) may be treated utilizing a procedure called percutaneous transluminal coronary angioplasty (PTCA). In a typical PTCA procedure, intravascular devices are inserted into the patient's vascular system at a remote access site such as the femoral artery near the groin. The intravascular devices are navigated through the femoral artery and the descending aorta, over the aortic arch, down the ascending aorta, and into the targeted coronary artery.

The path from the remote access site to the targeted coronary artery is established and maintained utilizing a conventional guide catheter and guidewire. The guide catheter extends from a point outside the patient's body, through the remote access site, to the ostium of the targeted coronary artery. The guidewire extends from a point outside the patient's body, through the guide catheter, and across the treatment site of the targeted coronary artery. A balloon catheter may then be advanced over the guidewire through the guide catheter until the distally mounted balloon is positioned across the treatment site. The balloon is then inflated to dilate the vascular restriction, thereby opening the artery and restoring blood flow.

Different types of balloon catheters are suitable for use in this type of procedure. Balloon catheters that are designed for use in combination with a guidewire as discussed above are typically referred to as over-the wire (OTW) or rapid exchange (RX) type balloon catheters. OTW and RX type balloon catheters include an elongate shaft having an inflation lumen and a guidewire lumen. In an OTW type balloon catheter, the guidewire lumen extends from the proximal end of the catheter to the distal end of the catheter. In an RX type balloon catheter, the guidewire lumen extends from a point distal of the proximal end to the distal end of

or more regions of modified flexibility extending longitudinally along the outer wall. Absent the regions of modified flexibility, the inner wall would create an imbalance of material and flexibility about the center axis of the shaft. The regions of modified flexibility are positioned to reduce any such imbalance, thereby providing more uniform flexibility, without compromising the fluid dynamic capabilities of the lumens. The regions of modified flexibility also provide for more uniform torque transmission, and thereby reduce whipping effects.

In one embodiment, the regions of modified flexibility comprise one or more regions of decreased wall thickness in the outer wall. In another embodiment, the regions of modified flexibility comprise one or more spines extending longitudinally along the outer wall. In yet another embodiment, the regions of modified flexibility comprise a combination of these features.

Brief Description of the Drawings

Figure 1 is a plan view of an intravascular device in accordance with the present invention, shown in the exemplary form of a balloon catheter;

Figure 2A is a cross-sectional view and Figure 3A is a partial isometric view of an embodiment of the elongate shaft of the intravascular device shown in Figure 1;

Figure 2B is a cross-sectional view and Figure 3B is a partial isometric view of another embodiment of the elongate shaft of the intravascular device shown in Figure 1;

Figure 2C is a cross-sectional view of a further embodiment of the elongate shaft of the intravascular device shown in Figure 1; and

Figure 2D is a cross-sectional view of yet another embodiment of the elongate shaft of the intravascular device shown in Figure 1.

Detailed Description of the Invention

The following detailed description should be read with reference to the drawings in which similar elements in different drawings are numbered the same. The drawings, which are not necessarily to scale, depict illustrative embodiments and are not intended to limit the scope of the invention.

Refer now to Figure 1, which illustrates a plan view of an intravascular device in the form of a balloon catheter 10. Those skilled in the art will recognize that the

As seen in Figure 2A, the portion of the outer wall 20 which defines the guidewire lumen 26 includes a thinned portion 28 extending longitudinally along the shaft 12A. The thinned portion 28 of the outer wall 20 has a wall thickness T_1 which is less than the wall thickness T_2 of the remainder of the outer wall 20. The thickness T_1 of the thinned portion 28 may also be less than the wall thickness T_3 of the inner wall 24. The reduced wall thickness T_1 of the thinned portion 28 compensates for the imbalance of material and flexibility relative to the center longitudinal axis of the elongate shaft 12A due to the inner wall 24. In Figure 2A, the center longitudinal axis of the elongate shaft 12A appears as a point (not shown) positioned at the geometric center of the outer wall 20. The provision of the inner wall 24 increases the amount of material on one side of the shaft 12A when viewed in cross section. The increased amount of material due to the inner wall 24 increases the rigidity along that side of the elongate shaft 12A, thereby causing non-uniformity in flexibility in different planes of flexure. By reducing the wall thickness T_1 in the thinned outer wall portion 28, the imbalance of material and flexibility due to the inner wall 24 is mitigated.

Because the thinned portion 28 of the outer wall 20 does not define any portion of the inflation lumen 22, the thinned portion 28 does not compromise the ability of the inflation lumen 22 to withstand high inflation pressures. In addition, the inner wall 24 may be shifted toward the thinned portion 28 of the outer wall 20 a distance approximately equal to T_2-T_1 without compromising the size of the guidewire lumen 26. Because the inner wall 24 may be shifted in the direction of the thinned portion 28 of the outer wall 20, the inflation lumen 22 also benefits from a corresponding increase in cross-sectional area, thereby improving fluid flow therethrough.

Refer now to Figure 2B, which illustrates a cross-sectional view of an elongate shaft 12B in accordance with another embodiment of the present invention. Also refer to Figure 3B, which illustrates an isometric view of a segment of the elongate shaft 12B. Except as illustrated and described herein, the elongate shaft 12B is substantially the same as elongate shaft 12A described with reference to Figures 2A and 3A.

Elongate shaft 12B includes an outer wall 20, an inner wall 24, an inflation lumen 22 and a guidewire lumen 26. Elongate shaft 12B may optionally include a thinned region 28 in the outer wall 20. Elongate shaft 12B further includes

smoother outside surface than elongate shaft 12B. Figure 2D illustrates an elongate shaft 12D having three longitudinal spines 30 uniformly spaced about the outer wall 20 opposite the inner wall 24 relative to the longitudinal center axis.

Those skilled in the art will recognize that the present invention may be manifested in a variety of forms other than the specific embodiments described and contemplated herein. Accordingly, departures in form and detail may be made without departing from the scope and spirit of the present invention as described in the appended claims.

10. An intravascular device as in claim 5, wherein the one or more spines are positioned, relative to the center longitudinal axis, opposite the inner wall.

11. An intravascular device as in claim 10, wherein the one or more spines are positioned equidistant from the inner wall.

12. An intravascular device as in claim 10, wherein the one or more spines are uniformly spaced.

13. An intravascular device comprising an elongate tubular shaft having an outer wall and an inner wall dividing the outer wall into first and second longitudinal lumens, and one or more spines extending longitudinally along the outer wall to compensate for an imbalance of material and flexibility about a longitudinal center axis of the shaft that would otherwise occur due to the inner wall.

14. An intravascular device as in claim 13, wherein the first lumen is larger than the second lumen.

15. An intravascular device as in claim 14, wherein the first lumen is crescent shaped.

16. An intravascular device as in claim 15, wherein the second lumen is circular.

17. An intravascular device as in claim 13, wherein the spines are integral with the outer wall.

18. An intravascular device as in claim 17, wherein the spines comprise regions of increased wall thickness in the outer wall.

19. An intravascular device as in claim 18, wherein the spines extend outwardly.

28. An intravascular device as in claim 27, wherein the spines are integral with the outer wall.

29. An intravascular device as in claim 28, wherein the spines comprise regions of increased wall thickness in the outer wall.

30. An intravascular device as in claim 29, wherein the spines extend outwardly from the outer wall.

31. An intravascular device as in claim 22, wherein the one or more regions of modified flexibility comprise a combination of one or more regions of decreased wall thickness in the outer wall and one or more spines extending longitudinally along the outer wall.

32. An intravascular device as in claim 31, wherein the one or more spines are positioned, relative to the center longitudinal axis, opposite the inner wall.

33. An intravascular device as in claim 32, wherein the one or more spines are positioned equidistant from the inner wall.

34. An intravascular device as in claim 32, wherein the one or more spines are uniformly spaced.

Fig. 1

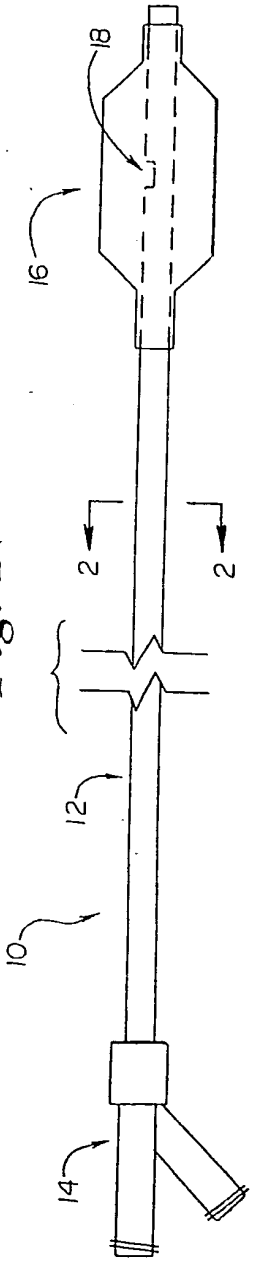


Fig. 3A

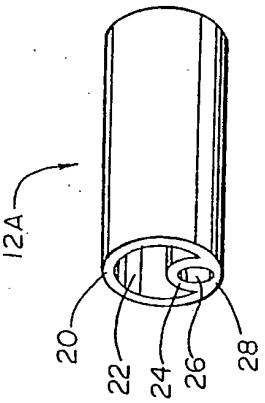


Fig. 2A

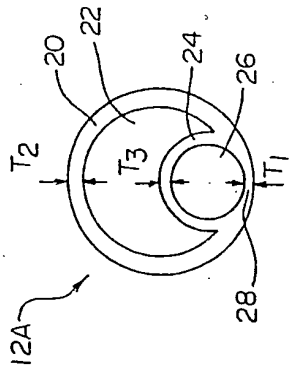


Fig. 3B

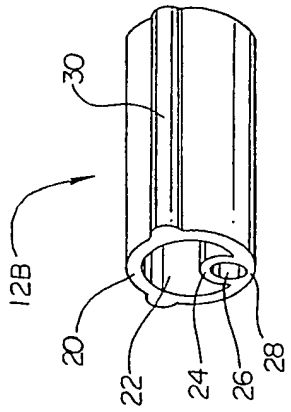


Fig. 2D

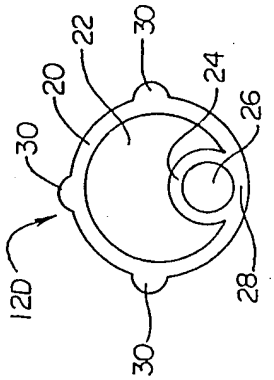


Fig. 2B

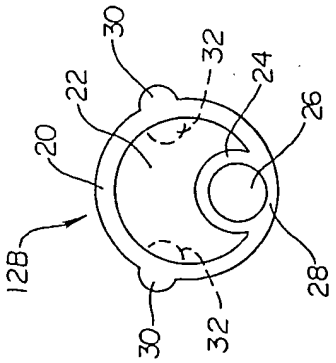
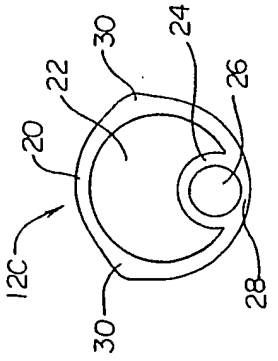


Fig. 2C



A. CLASSIFICATION OF SUBJECT MATTER
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According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

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IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 601 713 A (FUQUA CLARK R) 22 July 1986 (1986-07-22) column 8, line 19 - line 46; figures	1-7, 9-18, 20-29, 31-34
X	US 5 968 009 A (SIMAN JAIME E) 19 October 1999 (1999-10-19) column 3, line 41 -column 4, line 32; figures	1-3, 22-24,26
X	BE 689 333 A (FLEURY) 14 April 1967 (1967-04-14) page 4, paragraph 2; figures	1,2,22, 23,26

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
7 October 2002	14/10/2002

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Kousouretas, I